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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MARSCHEL, ARDIN H	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/728,327	JORGENSEN ET AL.	
	Examiner	Art Unit	
	Ardin Marschel	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,11-24,27-31,35 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,11-24,27-31,35,&36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *11/21/03*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 8/27/03, have been fully considered and they are deemed to be persuasive to overcome previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Unfortunately, upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

Due to the newly applied rejections, summarized below, the Finality of the Office action, mailed 5/27/03, is hereby withdrawn. The amendment, filed 8/27/03, has been entered and overcomes the previous rejections as noted in the Examiner Interview Summary of 21 November 2003. Regrettably, some delay has occurred in completing said reconsideration, however, the following rejections are deemed appropriate.

VAGUENESS AND INDEFINITENESS

Claims 9, 11-24, 27-31, 35, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 9, lines 1-2, indicates that the system is directed to processing cells maintained in a sterile environment. The actual components of the system cited in the remainder of claim 9 lacks any such maintaining of a sterile environment limitation(s). In lines 8-9 of claim 9 a set of conduits is cited for connecting various modules in a sterile manner. This lacks any maintaining practice as well as lacking any processing of biological cells in a sterile manner, maintained or not. In the

last two lines of claim 9 the prevention of unwanted contamination is set forth, but without any indication that such unwanted contamination is related to sterility. For example, contamination may be chemical in nature without biological cell contamination. Thus, the contamination limitation in said last two lines of claim 9 do not correspond to sterile environment condition(s) or any maintaining. The metes and bounds of claim 9 therefore is vague and indefinite as to whether the preamble controls said metes and bounds or whether the differing system components in lines 3 etc. of claim 9 control said metes and bounds. Claim 36 also contains this unclarity. Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claim 9 also contain this unclarity due to their dependence.

In claim 30, lines 1-4, various modules are cited as being contained within a cell processing system operated by the method of claim 30. One of these is a control module which is described as being provided with process data from several sensors. A control module is reasonably interpreted as being a module which controls something. Consideration of the entirety of claim 30 has failed to reveal any system component which is described as being controlled by said control module. Thus the control wording regarding said control module is vague and indefinite as to what control relationship that this module has with anything, specifically other system components as claimed in claim 30. Claim 35 also contains this same control module unclarity. Clarification via clearer claim wording is requested. Claim 31 which depends directly from claim 30 also contain this unclarity due to its dependence.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 30 and 31 are rejected under 35 U.S.C. 102(e)(2) as being clearly anticipated by Chupp et al. (P/N 5,812,419).

Chupp et al. summarizes the invention therein in the title and abstract as being directed to blood cell analysis from blood samples. In column 2, lines 45-50, a blood sample is obtained with a single blood draw from a patient. In column 57, lines 50-67, a blood sample is aliquoted via an aspiration probe, which aliquot is 75 microliters, is deposited for analysis. Such an aliquot is reasonably interpreted as a measured volumetric amount of cells which is less than the amount of biological cells provided in the whole blood sample module as required in instant claim 30, lines 6-8. The sample tube containing whole blood which contains biological blood cells is disclosed in column 57, lines 57-61, which is interpreted as providing as cited in instant claim 30, line 5. In column 58, lines 1-53, chemicals which are diluent and retic reagent is provided to the analysis cup containing the blood aliquot as well as then being processed via "(top level algorithm file mcCBCAlgorithm.cc)" as required in instant claim 30, lines 9-12. It is

noted that the diluent volume as well as the blood sample volume are measured as required in instant claim 30, lines 10-11, and instant claim 31. The storing of the blood cell sample in the HGB cup during sample and reagent dispensing and processing as described in column 58, lines 1-53, also anticipates the last 2 lines of instant claim 30 as such an analysis cup prevents unwanted contamination of the blood cells via containment therein for performing the analysis as described in the reference. Thus, instant claim 30 is anticipated by disclosures in Chupp et al.

Claim 36 is rejected under 35 U.S.C. 102(b) and (e)(2) as being clearly anticipated by Samuel et al. (P/N 5,399,314).

The title, abstract, and Figure 8 of Samuel et al. summarize the invention therein disclosed as being directed to a system for sterilizing an article or material in a chamber via introducing process chemicals in the form of a sterilizing gas or vapor into said chamber. In the FIELD OF THE INVENTION section in column 1 the sterilizing is described as being performed to destroy bacteria. In column 2, lines 56-62; and column 10, line 63, through column 11, line 22; the automatic control via measurements in the sterilizer of the invention is described. Various components of the sterilizer of Samuel et al. are depicted in Figures 1-9 as described in Samuel et al. in columns 7-11. The supply module portion of the system of Samuel et al. is described for the delivery of sterilizing gas or vapor in selected amounts as in lines 3-4 of claim 36 is set forth in column 3, lines 15-17, and column 7, line 61, through column 8, line 8. Samuel et al. discloses the cell sensing of amounts of biological cells during sterilization via sterilizing gas as in Samuel et al. in column 2, lines 1-16, as required also in claim 36, lines 5-6.

The sterile manner of sealing conduits, chemical supply, and biological cells within the process chamber of instant claim 36, lines 7-11, for processing the biological cells for sterilization is disclosed in column 7, line 48, through column 8, line 52, wherein the ethylene oxide injector is also totally sealed within the chamber. Sensors for biological cells as well as process chemicals are described in Samuel et al. in column 2, lines 1-16; column 3, lines 34-50; and column 9, line 18, through column 10, line 6; as required in instant claim 36, lines 12-15; wherein temperature sensing via infrared sensor usage is described in column 6, lines 39-44, and column 10, lines 54-58. The control module practice of instant claim 36, lines 16-19, is disclosed in Samuel et al. in column 10, line 63, through column 11, line 22. The sealing to prevent unwanted contamination as in instant claim 36, last 2 lines, was described above regarding sealing to provide a sterile manner of processing which is reasonably a type of preventing of unwanted contamination during processing.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9, 11, 14, 21, 22, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chupp et al. (P/N 5,812,419); taken in view of Yoshida (P/N 4,645,482); taken further in view of either of Inoue et al. (P/N 5,153,828) or Inaba et al. (P/N 5,403,279).

Chupp et al. has been summarized above regarding processing blood samples with supplying chemicals with controlling of transfer etc. but does not disclose therein the practices of sterility or weighing of supplied blood samples. Chupp et al., however, is noted as disclosing valving for the control of chemicals and blood samples for its analyzer practice in column 3, lines 52-65, and column 5, lines 58-59, as also required in instant claim 9, lines 10-11. Volumetric blood sample and chemical measurements including mixing via dilution were pointed to above in Chupp et al. as also required in instant claims 11, 14, and 21. Chupp et al. also describes a number of sensors being utilized such as optical (column 55, lines 30-42) as required in instant claim 22.

Yoshida is directed to blood sampling from patients via medical bag collection of blood which is well known in such methodology. In column 1, lines 17-20, the usage of sterilization in blood sampling practice is suggested and motivated for medical safety.

Both Inoue et al.(Figure 7 and associated description) and Inaba et al. (abstract) summarize the usage of weight of blood sampling as utilized for blood collection quantitation as motivated for accuracy of such collection.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to collect blood as in Inoue et al. or Inaba et al. utilizing weight measurements motivated by accuracy thereof as well as under sterile conditions

for medical safety as motivated by Yoshida wherein blood samples are then analyzed for a variety of components therein as in Chupp et al. to result in the practice of the instant invention as basically claimed in instant claims 9 and 35.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., AU 1631 Supervisory Patent Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 20, 2005

Ardin H. Marschel 3/20/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER